Revised 4/5/11

Werfen Group | Instrumentation Laboratory

APR - 5 2011

510(k) Summary
(per 21 CFR 807.92)

Applicant Contact Information:

Applicant:	Instrumentation Laboratory Co.
Address:	180 Hartwell Road Bedford, MA 01730
Contact Person:	Carol Marble, Regulatory Affairs Director
Phone Number:	781-861-4467
Fax Number:	781-861-4207
Preparation Date:	April 5, 2011

Device Trade Names (Products Sold Separately):

HemosIL® LA Positive Control

HemosIL® LA Negative Control

Device Regulatory Information:

Positive Control:	Class II	Product Code: GGN	21 CFR 864.5425
Negative Control:	Class II	Product Code: GIZ	21 CFR 864.5425

Predicate Devices:

K935254	LAtrol Abnormal Control and LAtrol Normal Control (Manufacturer: American Diagnostica)

Device Descriptions:

- HemosIL LA Positive Control

  The LA Positive Control is a lyophilized preparation from human donors exhibiting the presence of anti-phospholipid antibodies with added buffer, which has been determined to be positive for LA in accordance with the Guidelines from ISTH[1].

  The control assesses the precision and accuracy of Lupus Anticoagulant (LA) tests performed on IL Coagulation Systems using HemosIL LA assays.

- HemosIL LA Negative Control

  The LA Negative Control is a lyophilized preparation using human citrated platelet-poor plasma to make a Pooled Normal Plasma with added buffer. The guidelines from ISTH[1], recommends a platelet-poor plasma as a negative control for Lupus Anticoagulant (LA).

  The control assesses the precision and accuracy of Lupus Anticoagulant (LA) tests performed on IL Coagulation Systems using HemosIL LA assays.

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[1] *Update of the Guidelines for Lupus Anticoagulant detection (ISTH 2009) Journal of Thrombosis and Haemostasis, 2009, 7:1737-1740.*

Device Intended Uses:

- HemosIL LA Positive Control: For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family, ACL ELITE®/ELITE PRO/8/9/10000, ACL Futura/ACL Advance, ACL Classic (100-7000)].
- HemosIL LA Negative Control: For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family, ACL ELITE®/ELITE PRO/8/9/10000, ACL Futura/ACL Advance, ACL Classic (100-7000)].

Statement of Technological Characteristics of the Device Compared to Predicate Devices:

HemosIL LA Positive Control and HemosIL LA Negative Control are substantially equivalent to LAtrol Abnormal Control and LAtrol Normal Control (K935254).

Substantial Equivalence Comparison Table:

Characteristic	New Devices (Sold Separately): HemosIL LA Positive Control and HemosIL LA Negative Control	Predicate Devices: LAtrol Abnormal Control and LAtrol Normal Control (K935254)
Intended Use	• HemosIL LA Positive Control: For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family, ACL ELITE®/ELITE PRO/8/9/10000, ACL Futura/ACL Advance, ACL Classic (100-7000)]. • HemosIL LA Negative Control: For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family, ACL ELITE®/ELITE PRO/8/9/10000, ACL Futura/ACL Advance, ACL Classic (100-7000)].	The LAtrol Abnormal Control and LAtrol Normal Control plasmas have been developed for use as part of daily quality control procedures for Lupus Anticoagulant (LA) testing.
Analyte Being Tested	Lupus Anticoagulant	Same
Format	Lyophilized Plasma	Same
Constituent Material	• HemosIL LA Positive Control: Lyophilized preparation from human donors exhibiting the presence of anti-phospholipid antibodies with added buffer. • HemosIL LA Negative Control: Lyophilized preparation using human citrated platelet-poor plasma to make a Pooled Normal Plasma with added buffer.	• LAtrol Abnormal Control: Lyophilized preparation of a Lupus Anticoagulant plasma with Buffer. • LAtrol Normal Control: Lyophilized preparation of a multi-donor Normal plasma pool with Buffer.
Reconstituted Stability	24 Hours at 2-8° C	8 Hours at 2-8° C

Summary Performance Data:

Precision

Standard: **EP05-A2:** Evaluation of Precision Performance of Quantitative Measurement Methods, 2nd Edition, 08/20/2004

Materials: HemosIL LA Positive Control and HemosIL LA Negative Control (2 Lots of Each Control, with one representative lot shown on the following pages)
HemosIL LAC Screen and Confirm (K990302)
HemosIL Silica Clotting Time – Screen and Confirm (K050221)

Protocol: N=80 (2 replicates per run/2 runs per day/20 days) using two lots of each control level with two different LA assays* per instrument platform. The data from a representative lot of each control are shown on the following pages.

*NOTE: Only HemosIL LAC Screen/LAC Confirm was tested on the ACL Classic models (ACL 300+, ACL 3000 and ACL 6000). There is no test application on these models for HemosIL Silica Clotting Time.

Representative IL Coagulation Systems:

- ACL TOP Family Members: TOP (base model) and 500 CTS
- ACL 10000
- ACL Advance
- ACL 300+
- ACL 3000
- ACL 6000

Specifications:

- HemosIL LA Negative Control: Within run and Total ≤ 6% CV
- HemosIL LA Negative Control: Within run and Total ≤ 6% CV

Conclusion:

- All results were well within specification for both lots of controls tested.

Summary Performance Data (Cont.):

Precision

Instrument: **ACL TOP**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	32.1	0.6	1.4	1.6
	HemosIL LA Positive Control	N1190681	30.8	0.6	1.4	1.6
LAC Screen	HemosIL LA Negative Control	N1190682	32.9	0.5	0.5	0.9
	HemosIL LA Positive Control	N1190681	56.2	0.7	1.2	1.5
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	0.8	1.7	1.9
	HemosIL LA Positive Control	N1190681	1.64	1.0	2.1	2.5

Instrument: **ACL TOP**
Reagent: **HemosIL Silica Clotting Time (Screen/Confirm)**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
SCT Confirm	HemosIL LA Negative Control	N1190682	35.7	2.0	1.8	2.7
	HemosIL LA Positive Control	N1190681	37.3	1.9	1.0	2.4
SCT Screen	HemosIL LA Negative Control	N1190682	33.4	1.2	0.0	1.2
	HemosIL LA Positive Control	N1190681	75.0	2.3	0.0	2.7
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	2.3	1.4	2.8
	HemosIL LA Positive Control	N1190681	2.15	3.4	0.0	4.2

Summary Performance Data (Cont.):

Precision

Instrument: **ACL TOP 500 CTS**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	31.0	1.0	1.0	1.4
	HemosIL LA Positive Control	N1190681	32.2	1.0	0.9	1.4
LAC Screen	HemosIL LA Negative Control	N1190682	33.1	0.5	0.8	0.9
	HemosIL LA Positive Control	N1190681	56.3	0.6	1.1	1.3
Normalized Ratio	HemosIL LA Negative Control	N1190682	0.96	0.9	1.5	1.8
	HemosIL LA Positive Control	N1190681	1.58	0.9	1.5	1.8

Instrument: **ACL TOP 500 CTS**
Reagent: **HemosIL Silica Clotting Time (Screen/Confirm)**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
SCT Confirm	HemosIL LA Negative Control	N1190682	35.7	1.1	0.9	1.7
	HemosIL LA Positive Control	N1190681	36.8	2.5	0.0	2.6
SCT Screen	HemosIL LA Negative Control	N1190682	32.7	1.0	0.0	1.2
	HemosIL LA Positive Control	N1190681	74.1	0.9	1.2	1.6
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	1.5	0.0	2.0
	HemosIL LA Positive Control	N1190681	2.20	2.3	0.0	2.3

Summary Performance Data (Cont.):

Precision

Instrument: **ACL 10000**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	30.4	0.4	1.8	2.1
	HemosIL LA Positive Control	N1190681	31.9	0.8	1.5	2.0
LAC Screen	HemosIL LA Negative Control	N1190682	33.8	0.4	3.0	3.1
	HemosIL LA Positive Control	N1190681	58.1	2.3	2.9	3.7
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	0.6	2.7	2.8
	HemosIL LA Positive Control	N1190681	1.64	1.7	2.5	3.0

Instrument: **ACL 10000**
Reagent: **HemosIL Silica Clotting Time (Screen/Confirm)**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
SCT Confirm	HemosIL LA Negative Control	N1190682	34.3	0.8	0.9	1.2
	HemosIL LA Positive Control	N1190681	33.6	0.8	0.7	1.2
SCT Screen	HemosIL LA Negative Control	N1190682	32.0	1.4	0.7	1.8
	HemosIL LA Positive Control	N1190681	69.5	2.3	0.9	3.0
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	1.6	1.2	2.2
	HemosIL LA Positive Control	N1190681	2.22	2.3	1.6	3.2

Summary Performance Data (Cont.):

Precision

Instrument: **ACL Advance**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	28.7	0.9	2.1	2.3
	HemosIL LA Positive Control	N1190681	30.1	0.8	1.8	1.9
LAC Screen	HemosIL LA Negative Control	N1190682	32.0	0.8	1.1	1.7
	HemosIL LA Positive Control	N1190681	53.1	1.2	2.0	2.4
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	2.7	1.8	3.9
	HemosIL LA Positive Control	N1190681	1.58	1.6	2.8	3.3

Instrument: **ACL Advance**
Reagent: **HemosIL Silica Clotting Time (Screen/Confirm)**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
SCT Confirm	HemosIL LA Negative Control	N1190682	31.8	1.9	0.0	2.2
	HemosIL LA Positive Control	N1190681	32.3	2.1	2.0	2.9
SCT Screen	HemosIL LA Negative Control	N1190682	32.2	1.1	1.1	1.7
	HemosIL LA Positive Control	N1190681	69.2	2.0	1.6	2.9
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	1.6	0.8	2.0
	HemosIL LA Positive Control	N1190681	2.12	3.5	2.3	4.2

Summary Performance Data (Cont.):

Precision

Instrument: **ACL 6000**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	30.9	1.1	1.1	1.6
	HemosIL LA Positive Control	N1190681	32.0	0.6	1.1	1.5
LAC Screen	HemosIL LA Negative Control	N1190682	32.9	0.3	0.9	0.9
	HemosIL LA Positive Control	N1190681	56.5	0.5	1.1	1.2
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	1.1	1.4	1.9
	HemosIL LA Positive Control	N1190681	1.66	0.7	1.1	1.8

Instrument: **ACL 3000**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	30.9	0.4	0.8	1.3
	HemosIL LA Positive Control	N1190681	33.8	0.3	0.9	1.1
LAC Screen	HemosIL LA Negative Control	N1190682	32.1	0.3	0.7	1.2
	HemosIL LA Positive Control	N1190681	57.1	1.0	1.1	1.6
Normalized Ratio	HemosIL LA Negative Control	N1190682	1.00	1.2	1.0	2.1
	HemosIL LA Positive Control	N1190681	1.64	0.9	0.7	1.6

Summary Performance Data (Cont.):

Precision

Instrument: **ACL 300+**
Reagent: **HemosIL LAC Screen/Confirm**

Reagent	Control	Control Lot No.	Grand Mean(s)	CV% Within Run	CV% Between Run	CV% Total
LAC Confirm	HemosIL LA Negative Control	N1190682	31.9	0.3	1.1	1.7
	HemosIL LA Positive Control	N1190681	32.9	0.4	1.0	1.6
LAC Screen	HemosIL LA Negative Control	N1190682	34.0	0.3	1.0	1.0
	HemosIL LA Positive Control	N1190681	58.2	0.8	1.1	1.7
Normalized Ratio	HemosIL LA Negative Control	N1190682	0.98	0.5	1.3	1.9
	HemosIL LA Positive Control	N1190681	1.63	2.0	0.8	2.6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Instrumentation Laboratory Co.
c/o Ms. Carol Marble
Regulatory Affairs Director
180 Hartwell Road
Bedford, MA 01730

APR 0 5 2011

Re: k102552
Trade/Device Name: HemosIL® LA Positive Control and HemosIL® LA Negative Control
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGC, GIZ, GGN
Dated: March 29, 2011
Received: March 30, 2011

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Leena Philip

For Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K102552

Device Name: HemosIL® LA Positive Control
HemosIL® LA Negative Control

Indications for Use:

- HemosIL LA Positive Control

  For use as an LA Positive Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

  The control assesses the precision and accuracy of Lupus Anticoagulant (LA) tests performed on IL Coagulation Systems using HemosIL LA assays.

- HemosIL LA Negative Control

  For use as an LA Negative Quality Control of Lupus Anticoagulant assays (HemosIL LAC Screen/LAC Confirm; HemosIL Silica Clotting Time) on IL Coagulation systems [ACL TOP® Family; ACL ELITE®/ELITE PRO/8/9/10000; ACL Futura/ACL Advance; ACL Classic (100-7000)].

  The control assesses the precision and accuracy of Lupus Anticoagulant (LA) tests performed on IL Coagulation Systems using HemosIL LA assays.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) 102552